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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,348	01/30/2004	Ramachandran Thembalath	IPCA	6363

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,348	THEMBALATH ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in India on 04/17/03, 09/18/03, and 10/31/03. It is noted, however, that applicant has not filed a certified copy of the foreign priority applications as required by 35 U.S.C. 119(b).

Specification

The abstract of the disclosure is objected to because the specification does not disclose the following limitations:

The term "approximately" in claims 27, 30, 32, 34 and 36;

Step C in the process for manufacturing a substantially moisture stable pharmaceutical product;

The limitation "pharmaceutical-acceptable coating comprises a gelatin capsule" in claim 29; and

The limitations "[a] substantially moisture stable core comprising a drug substance, ethyl cellulose and surfactant", and "outer layer substantially free of said drug substance".

Although the Preliminary Amendment filed at the same time the application is filed is part of the original disclosure, the limitations recited in the amended claims is suggested to be incorporated into the specification. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "non-controlled release". In contrast, applicant's specification discloses a film coating made of hydrophobic coating materials such as hydroxypropyl methyl cellulose (HPMC) to help retard against degradation. One of the causes for degradation is the acid pH in the stomach. Thus, many acid labile drugs are coated with hydrophobic materials to control the release of the drug in the GI tract. This fact is evident by the teachings of Dahlinder et al. US 4,927,640 at column 3, lines 10-18). Accordingly, the instant specification does not provide support and/or guidance as to how the hydrophobic coating formulation of the instant invention can be a non-controlled release formulation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buxton et al. US 5,601,845, in view of Patel et al. US 6,248,363 and Chen et al. US 6,270,805.

Buxton teaches a coating composition comprising ethyl cellulose, polysorbate 80 as a surfactant, plasticizer, and mixture of solvent selected from dichloromethane, ethanol, methanol, acetone, and isopropyl alcohol (see abstract, column 2, lines 31-67, and column 3, lines 3-9). Buxton also teaches the process comprising mixing the ingredients of the coating composition, applying the coating to a drug spheroid core, the coated spheroid is filled into gelatin capsule (column 4, lines 1-25).

Buxton does not expressly teach non-controlled release dosage form.

Patel teaches an oral dosage form comprising paroxetine and salts thereof (column 6, lines 60; and claim 12). The dosage form is coated with ethyl cellulose and HPMC for a variety of reasons (column 42, lines 22-28). Thus, it would have been

obvious to one of ordinary skill in the art to modify the coating of Buxton using the seal coat in view of the teaching of Patel to obtain the claimed invention, because Buxton teaches the use of ethyl cellulose as a suitable coating polymer, and because Patel teaching a seal coating using the claimed polymer for a variety of reasons, *e.g.*, particle porosity reduction, reduce dust, chemical protection, mask taste, reduce odor, and the like (column 42, lines 22-28).

In the case that applicant argues that Patel teaches paroxetine hydrochloride in a long list.

Chen teaches a controlled release formulation for water-soluble drugs include diltiazem, and paroxetine hydrochloride (column 3, lines 3-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the spheroid formulation of Buxton using paroxetine in view of the teaching of Chen, because Chen teaches the similarity of water-soluble drugs including diltiazem and paroxetine (column 3, lines 3-9), and because Buxton teaches a controlled release formulation for diltiazem.

The cited references do not teach the claimed ratio between polysorbate 80 and ethyl cellulose. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amounts of polysorbate 80 and ethyl cellulose to

obtain the claimed invention, because Buxton teaches the use of ethyl cellulose as a suitable coating polymer and polysorbate 80 as a suitable surfactant in a controlled release formulation, and because Chen teaches the use of ethyl cellulose as a coating polymer useful to control the release rate of water-soluble drug.

Response to Arguments

Applicant's arguments filed 03/14/06 have been fully considered but they are not persuasive.

Applicant argues that the cited references fail to teach the claimed invention because of the teachings of the controlled release. In response to applicant's argument, Buxton is cited in view of Patel for the teaching of multiple functions of ethyl cellulose coating composition.

Applicant argues that there is no motivation to combine the references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the cited references teach the use of ethyl cellulose coating composition is known in pharmaceutical art for its multiple characteristics.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Examiner
Art Unit 1615